RIDA®TUBE

REF GZ3013

R-Biopharm AG, An der neuen Bergstrasse 17, 64297 Darmstadt, Germany
+49 (0) 61 51 81 02-0 / +49 (0) 61 51 81 02-20 / www.r-biopharm.com

1. Intended use

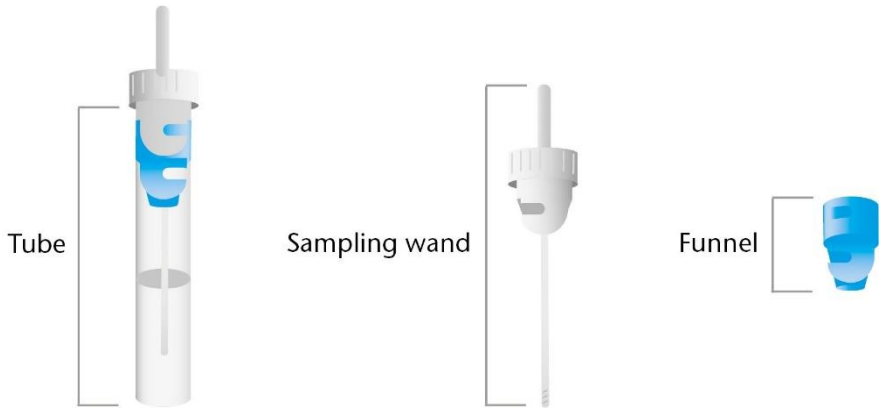
For *in vitro* diagnostic use. The RIDA®TUBE vials are unfilled stool collection tubes for the extraction of stool samples in the laboratory.

The tests results should not be used as the sole basis for diagnosis. The product is intended for professional use.

2. Summary and explanation of the accessories

One RIDA®TUBE consists of the following parts:
- Tube
- Sampling wand with sampling tip
- Funnel

Components:



3. Reagents provided

One package contains 50 vials and 50 sampling wands.

4. Storage instructions

Please follow the handling guidelines in Table 1 and store the kit directly after use according to the information specified. After the expiration date has passed or the recommended storage period of the opened reagents has elapsed, the quality guarantee is no longer valid.

Table 1: Storage conditions and information

	Storage temperature	Maximum storage time	Additional notes on storage
unopened	2 - 25 °C	Can be used until the printed expiration date	–
opened	2 - 25 °C	Can be used until the printed expiration date	–

5. Reagents required but not provided

5.1 Reagents

Not applicable.

5.2 Laboratory equipment

The following accessories are needed for preparing samples using the RIDA®TUBE vials:

Equipment
Vortex mixer
Inoculation loop (optional)
Wooden applicator sticks

6. Warnings and precautions for the users

Only qualified laboratory personnel may use this product.
The guidelines for working in medical laboratories (good laboratory practice) must be followed. Always adhere strictly to the operating manual when collecting samples. Do not pipette samples or reagents using your mouth. Avoid contact with broken skin and mucous membranes. Wear personal protective equipment (appropriate gloves, lab coat, safety glasses) when handling reagents and samples, and wash hands after completing the test. Patient samples should be treated as potentially infections. Do not smoke, eat, or drink in areas where samples are handled. Centrifuging the RIDA®TUBE is not recommended. Users are responsible for the proper disposal of all reagents and materials after use. For disposal, please adhere to national regulations.

For users in the European Union: Report all serious adverse events associated with the product to R-Biopharm AG and the appropriate national authorities.

7. Collection and storage of samples

The collection and storage of samples is based on the analytes, their stability, and the extraction buffer used.

The sampling tip collects approximately 10 mg of stool sample. The maximum extraction buffer filling volume is 2.5 mL.

8. Test procedure

8.1. General information

Prior to collection, stool samples should have reached room temperature (20 - 25 °C) and be homogenized, e.g., through stirring with an inoculation loop or a wooden stick.
When transferring the sample into the stool vial, make sure that the grooves in the sampling tip are completely filled with stool. No stool should be on the wand of the sampling tip.
Once used, the stool vials must not be reused. Also, do not use stool vials if the packaging is damaged or the vials are leaking. The test must not be carried out in direct sunlight.

8.2. Filling of the RIDA®TUBE with buffer

Take note: The sampling tip collects approximately 10 mg of stool sample. The maximum extraction buffer filling volume is 2.5 mL.

1. Filling the tube with buffer before sample collection is recommended.
2. Open the tube by turning the blue bayonet lock counterclockwise and remove the white sampling wand, including the blue funnel, from the tube.
3. After having been filled with the respective buffer, the tube with the blue funnel, along with the white sampling wand, must be closed by turning the cap clockwise. The storage conditions of the filled tube are based on the storage conditions of the buffer used.

8.3. Sample collection using stool vials - procedure

1. After filling the RIDA®TUBE, remove the white sampling wand from the tube by rotating counterclockwise. Secure the blue funnel between thumb and index finger. The blue funnel must stay on the tube.
2. Dip the sampling tip into the stool sample at three different places.
3. Make sure that the grooves on the sampling tip are filled with stool.
4. Place the wand with the sampling tip back into the tube. Excess stool sample remains in the blue funnel. Close the tube by turning the cap clockwise. The sampling tip collects approximately 10 mg of stool sample. If the stool sample is liquid, 10 µL of the stool sample can be taken using the pipette and pipetted directly into the extraction buffer.
5. Before the start of the test, the tube is vortexed until the stool sample from the sampling tip is completely suspended in the extraction buffer. If the stool is very hard, it is recommended to tap the tube lightly against a solid surface until the stool is removed from the grooves.
6. Allow the extracts to settle. The RIDA®TUBE should not be centrifuged.
7. To start the test, unscrew the tube at the blue bayonet lock and remove the funnel and white sampling wand from the tube. The stool extract can now be removed from the tube.

Note: Users are responsible for validating the RIDA®TUBE in combination with other IVD devices. The RIDA®TUBE can also be used on automated ELISA systems, such as Dynex (DSX and DS2). If the RIDA®TUBE needs to be used in connection with automated ELISA systems, please contact R-Biopharm AG or your local distributor.

9. Version history

Version number	Section and designation
2017-09-22	Previous version
2022-03-03	General revision 1. Intended use 2. Summary and explanation of the test 3. Reagents provided 4. Storage instructions 5. Reagents required but not provided 6. Warnings and precautions for the users 7. Collection and storage of samples 8. Test procedure

10. Explanation of symbols

General symbols

	For in vitro diagnostic use
	Observe operating manual
	Batch number
	Use before
	Storage temperature
	Item number
	Number of tests
	Date of manufacture
	Manufacturer
	Do not reuse